EXHIBIT A

Yale school of public health

ysph.yale.edu/profile/harvey-risch harvey.risch@yale.edu

Nathan J. Arnold Arnold Jacobowitz & Alvarado PLLC 8201 164th Ave NE, Ste. 200 Redmond, WA 98052

Re: Ruthann Shirley et al. v. Washington State Department of Fish and Wildlife ("WDFW") et al. Case

Dear Mr. Arnold:

I have compiled in the following discussion my initial thoughts and opinions regarding the WDFW Case. At your request, I have reviewed various particulars and materials of the case. The opinions I set forth in this report are based upon my education and experience and my understandings of the relevant scientific literature, and all of my discussions herein I hold to a reasonable degree of medical and scientific certainty. I start with my professional training and experience as an epidemiologist, and then for background cover various general scientific points of relevance as shown in sections titled by headings. Finally, I discuss some issues directly pertaining to the case.

Professional Training and Experience

I am Professor Emeritus of Epidemiology at Yale School of Public Health, an elected Fellow of the American College of Epidemiology, and an elected member of the Connecticut Academy of Science and Engineering. I am a practicing epidemiologist with more than 40 years of research and teaching experience.

I have taught introductory, intermediate and advanced epidemiologic research methods to generations of MPH and PhD students and postdoctoral fellows in public health. I have for some years also taught courses on pharmacoepidemiology, which is the epidemiologic study of medications, medical devices and vaccines and their antecedent and predisposing conditions.

Majoring in both mathematics and biology, I received a Bachelor of Science degree from the California Institute of Technology in 1972 and completed medical training at UC San Diego School of Medicine in 1976. I then completed a PhD in biomathematics in 1980 at the University of Chicago, where my dissertation work involved studies of the general stochastic epidemic model, on which I have published in the peer-reviewed scientific literature (https://www.sciencedirect.com/science/article/abs/pii/0025556483900470). My coursework in graduate school included advanced probability, statistics, population genetics, infectious diseases, and ecology. Following my graduate work, I did a three-year postdoctoral fellowship in epidemiology at the School of Public Health and Community Medicine at the University of Washington in Seattle, where I sat for additional coursework in chronic- and infectious-disease epidemiology and in biostatistics.

Over my professional career, I have published approximately 400 peer-reviewed original research papers in very well-regarded scientific journals and have an h-index of 116, with more than 55,000 publication citations to-date. I have been Associate Editor of the *Journal of the National Cancer*

Institute since 2000, Member of the Board of Editors of the *American Journal of Epidemiology* from 2014-2020, and Editor of the *International Journal of Cancer* since 2008.

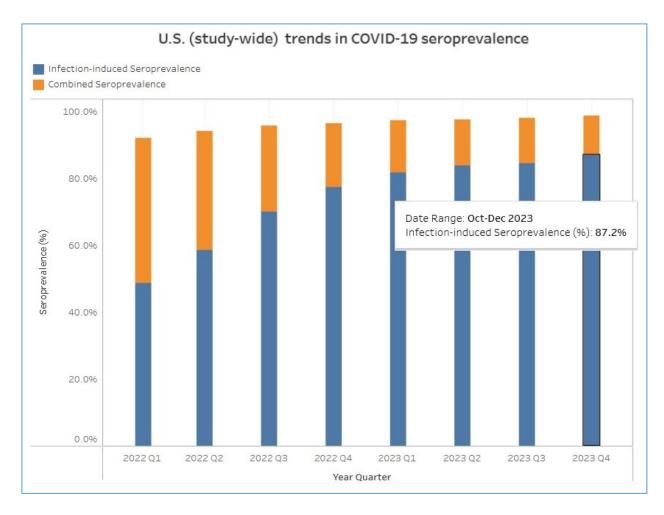
In May 2020, I published the seminal review paper on early treatment of high-risk Covid-19 outpatients in the *American Journal of Epidemiology* (https://doi.org/10.1093/aje/kwaa093), which has been downloaded more than 91,000 times and viewed by more than 168,000. I updated that analysis with a thorough review and meta-analysis through June 2021 (https://earlycovidcare.org/wpcontent/uploads/2021/09/Evidence-Brief-Risch-v6.pdf). I was senior author on the outpatient treatment clinical trial study in Brazil (https://doi.org/10.1016/j.tmaid.2020.101906), and have coauthored with Dr. Peter McCullough a number of papers, including two that form the now-standard understanding of early outpatient Covid-19 management (https://doi.org/10.1016/j.amjmed. 2020.07.003 and https://rcm.imrpress.com/EN/10.31083/j.rcm.2020.04.264).

In other respects, while the majority of my career research has focused on various types of cancers as outcomes of interest, that work has involved the examination of a host of potential causal factors, including medications and infectious diseases. I was prepared to do research involving these risk factors by my medical education which included arguably one-quarter of its coursework on infectious diseases, and another similar amount on biochemistry, molecular and cellular biology, pharmacology, immunology and pathology.

Background: Public Health Management of the Covid-19 Pandemic

In general terms, the Covid-19 pandemic should not have been managed by reliance on counts of infections or cases, but on counts of deaths, hospitalizations and serious long-term syndromes caused by the infection, and by serious health, economic and psychological harms caused by the policies and actions taken in response to the pandemic, in that order of decreasing priority. The fact that apparent case occurrence correlates with these severe outcomes is not a justification of its use as an actionable measure of interest, because estimates of Covid-19 infection mortality range below 0.1% averaged across the age span (https://unherd.com/newsroom/how-wrong-was-i-on-covid-ifr/), and post-infection natural immunity serves a public good in post-hoc protecting people from severe reinfection for the overwhelming majority of people who do not develop long-term serious sequelae of infection.

Nevertheless, on September 27, 2021, Washington Governor Jay Inslee issued Emergency Proclamation 21-14.2 (https://governor.wa.gov/sites/default/files/proclamations/21-14.2%20-%20COVID-19%20Vax%20Washington%20Amendment%20(tmp).pdf), mandating Covid-19 vaccination for various classes of workers in the state. The motivation for the vaccine mandate stated in the proclamation was, "WHEREAS, COVID-19 vaccines are effective in reducing infection and serious disease, and widespread vaccination is the primary means we have as a state to protect everyone ... from COVID-19 infections;" [bolding mine]. However, by the end of 2023, CDC reported (see figure at top of next page) that cumulatively more than 87% of Americans had been infected with Covid-19 in spite of the massive, prolonged and booster-repeated national vaccination campaign (https://covid.cdc.gov/covid-data-tracker/#nationwide-blood-donor-seroprevalence-2022). My point is that by prioritizing numbers of infections rather than the more serious but less common consequences of both infections and policy harms, this and other vaccine mandate proclamation policies failed their main terms of reference in that more than 87% of Americans eventually became infected anyway.



Post-infection Natural Immunity vs Vaccine Immunity Against Covid-19

Most Covid-19 vaccination mandates, including the one issued by Governor Inslee, have ignored the role that post-infection "natural" immunity plays in helping to control the adverse consequences of the pandemic. With an organism of reproduction transmission R_0 of approximately 3 (original strain) or more than 6 (Delta; 10 for Omicron) (Karimizadeh et al., 2023), sustained natural and vaccine effectiveness against transmission would have had to remove infection susceptibility from some 83% or more people in the population (i.e., 1-1/6)—e.g., for vaccination to have indefinitely lasting efficacy against transmission above 90% in a population more than 90% vaccinated—in order to terminate the spread, and achieving these degrees of both vaccination uptake and vaccine performance were unrealistic during the pandemic. Thus, it was inevitable and apparent by the arrival of the Delta strain in summer 2021 that the overwhelming majority of the population would eventually get infected with the virus at some point. While post-infection population herd immunity likely slowed the spread, neither it nor vaccine immunity were ever able to control the spread of the infection overall. Nevertheless, that fact is not of policy consequence, because case count is not and should not have been the main public health priority—spread per se is not the issue—rather, the consequences of the spread and the negative consequences of the policies should have been the priorities.

Some quarters have argued that post-infection immunity may be less effective in controlling Covid-19 spread than post-vaccine immunity and may be shorter-lived than the latter. Of course, immunity to an infectious disease after survival from it has been known since the ancients, and post-

SARS-CoV-2 infection immunity generates antibodies to a range of viral antigens, not just to the spike protein, the genetically coded active moiety in the mRNA vaccines. This is how antibody testing such as in the figure on the previous page (https://covid.cdc.gov/covid-data-tracker/#nationwide-blood-donor-seroprevalence-2022) is able to distinguish natural immunity (test results positive for both anti-nucleocapsid and anti-spike antibodies) from vaccine-based immunity (tests negative for anti-nucleocapsid antibodies but positive for anti-spike antibodies). Natural post-infection immunity generates a much wider range of antibody responses than vaccine immunity and thus would be expected to be as good if not better than vaccine immunity. However, determination of such performance is best left to empirical quantitative and comparison studies, as follows.

Mao and colleagues (<u>Mao et al., 2022</u>) carried out a meta-analysis of studies of reinfection risks in patients previously infected with SARS-CoV-2. This paper was published on-line December 13, 2021, but the 19 studies included in its meta-analysis had already been published through May 1, 2021. In that meta-analysis, among the followed cohorts totaling 325,225 people who had had Covid-19, 1,096 reinfections were noted, for a risk of 0.34% in the pre-Delta Covid-19 period. Three more studies of reinfections were published in April-June 2021 (<u>Letizia et al., 2021</u>; <u>Vitale et al., 2021</u>; and <u>Abo-Leyah</u> et al., 2021), one in November (<u>Kojima et al., 2021</u>) and a fifth in December (<u>Chemaitelly et al., 2021</u>), bringing the total reinfection risk estimate to 1,242/372,368 = 0.33%, about 1 in 300 post-infection individuals. Durations of follow-up in these studies were all greater than 90 days save one study, and a number of studies followed subjects for 4-6 months or more.

A later meta-analysis of reinfection studies (COVID-19 Forecasting Team, 2023) estimated that protection against ancestral, Alpha, and Delta reinfection averaged about 85% and lasted at this level for some nine months before starting to wane. This study found that specifically for the Delta period, post-infection immunity conveyed an average of 82% reduced risk of reinfection, 85% reduced risk of symptomatic reinfection, and greater than 97% reduced risk of severe disease. This overwhelmingly reduced risk of severe disease is why post-infection natural immunity is such an important component of the proper public health management of the pandemic, the public good, as noted previously. I am not arguing that people should have sought to be infected in order to obtain post-infection immunity, but given that it was clear by mid-2021 that almost everyone would eventually get infected at some point, recognition of this fact should have played a practical role in the management of the pandemic.

Head-to-head comparisons of post-infection (reinfection) vs post-vaccination (breakthrough) infection risks have also been carried out. These studies properly have compared reinfection risks in unvaccinated individuals with breakthrough infection risks in people who have never had Covid-19. In a meta-analysis published on October 28, 2021 of seven studies, largely in the pre-Delta period, risk of infection was reduced 1.86-fold for Covid-recovered vs vaccinated uninfected people (Shenai et al., 2021). In a CDC study published January 19, 2022, for the Delta period from July through November 2021, risks of both laboratory-confirmed Covid-19 infection and of Covid hospitalization were 2-4-fold greater in people vaccinated with no previous Covid-19 diagnosis, vs individuals unvaccinated but with previous Covid diagnosis (León et al., 2022). Also in the Delta period, a study of 92,000 people in Israel published August 25, 2021 found a 5.96-fold increased risk of previously uninfected breakthrough infection vs unvaccinated reinfection (Gazit et al., 2021; Gazit et al., 2022). This study observed eight individuals with Covid-related hospitalizations, all in the vaccinated group. Finally, in a large US study of Covid-19 emergency department/urgent care (ED/UC) encounters during the Delta period, protection was 85% (95% CI 81%-87%) for unvaccinated people with documented prior infection, vs 72% (95% CI 70%-74%) for 2-dose mRNA vaccination without documented prior infection (Bozio et al., 2023). Prior infection was also more protective than 2-dose

vaccination in the Omicron period in this study. These studies clearly show that during the time leading up to the Washington state and WDFW vaccine mandates, having had Covid-19 was as or more protective against subsequent infection and against serious reinfection disease than vaccination without a previous Covid infection, and much of this knowledge was publicly available in that time frame. Documented fact of previous Covid-19 infection however was not included in the state vaccine mandate proclamation or in any reasoning therefrom about vaccination as the only invoked method to manage the pandemic.

Breakthrough Covid-19 Infections as Vaccine Failure

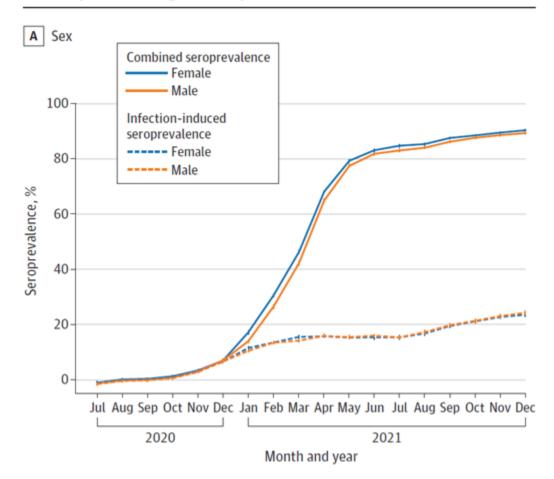
First, I note what should be obvious, that any Covid-19 vaccine efficacy short of 100% means that some vaccinated people will still get the infection. At the beginning of the vaccine roll-out, the initial randomized controlled trial (RCT) studies of vaccine efficacy claimed them to be 94-95% effective against symptomatic infection (Polack et al., 2020; Baden et al., 2021). These numbers imply that 5-6% of vaccinated people will get breakthrough infections. However, these efficacy claims were spuriously high, because these and other vaccine efficacy studies improperly did not attribute incident Covid -19 cases occurring within 7-21 days after vaccination to the vaccinated arm of the trial, and in some instances, they were attributed to the unvaccinated arm. In RCTs, adverse events are always attributed to the arm of assignment no matter when they occur after randomization, even, for example, if before the trial intervention takes place. This mis-attribution leads to excessively high vaccine efficacy estimates, even when a vaccine may have no efficacy whatsoever (Neil et al., 2024).

Generally, the stated goals of Covid-19 vaccination mandates have been in various instances to prevent public exposures to the virus. However, vaccination mandate policies should have sought to attempt to prevent the substantial *transmission* of Covid-19 infection. Exposure to Covid-19 is not the same as transmission, and this is not a facile distinction. Exposure is only relevant to the degree that it results in transmission, but transmission is the crucial endpoint, for that is, by definition, the spread of the infection from an infected person to exposed susceptible individuals. By late 2021, about 90% of the general population had either had Covid-19 infection (about 25%) or had been vaccinated against it (another 65%; Jones et al., 2022), thus for many if not most individuals, by that time, exposure per se would not have resulted in clinical infection, and thus not transmission.

Numerous factors affect the degree of Covid-19 transmission in workplace, educational and other public settings. In the absence of vaccination mandates, employees and others were still free to choose to be vaccinated, thus could have chosen to use vaccination as a method to prevent transmission to themselves. Contraindications to getting vaccinated against Covid-19 are rare. According to public CDC guidance at the time (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Contra indications), medical conditions putting people at high risk of adverse infection outcome are not contraindications to vaccination. The only contraindication is "History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine." CDC also lists certain *precautions*: history of a *non*-severe allergy as above, or acute illness (which is a temporary precaution). The precaution "History of myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine." is really a contraindication, but only against further Covid-19 vaccination.

The question at hand therefore in the WDFW vaccine mandate is to what degree mandating vaccination, over and above recommending it and allowing employees to choose whether to be vaccinated, served to reduce transmission in a major, substantial way.

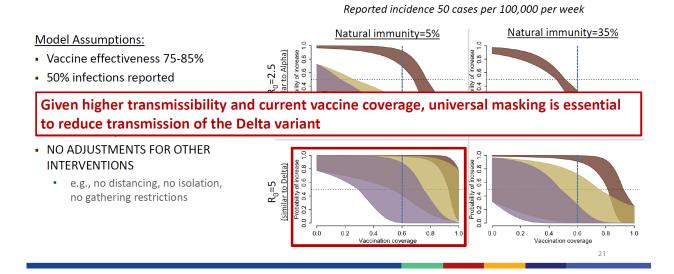
Figure 1. SARS-CoV-2 Seroprevalence by Census Region, Race and Ethnicity, Sex, and Age, US, July 2020-December 2021



To my understanding, by the latter half of 2021 and increasingly thereafter, two doses of the Covid-19 vaccines in general use lost most of their ability to reduce risk of infection transmission (Madewell et al., 2022). In that period, the Delta variant of SARS-CoV-2 was the predominant strain in general circulation, overtaking Alpha and previous strains in May-June 2021 and then itself overtaken by Omicron strains in December 2021-February 2022 (Christensen et al., 2022). Both Delta and Omicron started with large waves of infection even with the degrees of population vaccination and post-infection immunity present in the population at the times of their arrival.

Additional evidence that the Covid-19 mRNA vaccines were failing to suppress infection spread in the Delta period of 2021 is seen in the CDC blood donor infection seroprevalence data from that period (Jones et al., 2022). The figure above from that paper shows that the estimated cumulative fraction of Americans infected with Covid-19 (seroprevalence, dashed lines) was increasing through March 2021 but then started slowing as the vaccine rollout progressed, and it plateaued from March through July 2021. But then when Delta started to spread and became dominant, August through December 2021, infections were again rising like in September through December 2020, in spite of the large degree of vaccination uptake that had already happened by that point (about 65% of people, the difference between the dashed and solid lines in the latter half of 2021). These empirical CDC

Given increased transmissibility, lower VE, and current vaccine coverage, NPIs needed to reduce transmission of Delta variant



data provide important evidence that the vaccines did reduce infection risk in the first half of 2021, but also that they increasingly failed to do so in the second half of 2021

In order to transmit the Covid-19 infection, a person must first be infected. That infection may or may not be recognized as symptomatic. Vaccine effects on getting symptomatic Covid-19 infection were studied by the manufacturers and in numerous post-marketing RCT studies. However, vaccine effects on infection transmission were explicitly not studied by the vaccine manufacturers in their RCT studies (Terhes, 2022). To clarify, I am referring to the effect of vaccination on infection source control, i.e., whether previous vaccination reduces the infected person's risk of secondarily transmitting the infection to others. Because of the requirement first to be infected, vaccine effects on transmission might seem to correlate with vaccine effects on infection risks, but they are not the same and require independent empirical data.

Appreciable amounts of empirical data have now demonstrated the Covid-19 vaccines' weakened performance in reducing secondary transmission during the second half of 2021. This is in part due to failures to stop post-vaccination breakthrough infections, and to weak ability to limit the intensity or infectiousness of breakthrough infections so that they are intrinsically less transmissible.

First, by the end of July 2021, CDC was already aware of and alarmed at the Covid-19 vaccines' inadequate performance in reducing transmission of the Delta variant, and made those observations public (McMorrow CDC presentation slide, 2021, above; the red box is original to the slide). At that time, there were increasing data and public knowledge that breakthrough infections were occurring in appreciable numbers of vaccinated individuals.

Published July 31, 2021, infected persons with Covid-19 in the Delta period were observed to have similar viral loads, whether or not they had previously been vaccinated (<u>Riemersma et al., 2021</u>). It was later observed that infected vaccinated individuals "clear[ed] detectable infections roughly 27% sooner than unvaccinated individuals" (<u>Puhach et al., 2023</u>). However, this fact cannot account for

Month	Cases Fully Vaccinated	Cases Partly Vaccinated	Total Cases Vaccinated	Cumulative Population Vaccinated
Apr 2021	31,754	104,783	136,537	60,098,934
May 2021	27,018	31,651	58,669	88,310,076
Jun 2021	36,366	14,084	50,450	106,187,806
Jul 2021	219,707	47,231	266,938	112,135,161
Aug 2021	588,827	158,797	747,624	116,720,587
Sep 2021	659,110	146,465	805,575	125,638,445
Oct 2021	384,672	52,092	436,764	130,808,622
Nov 2021	456,495	61,383	517,878	134,115,910
Dec 2021	2,701,465	266,736	2,968,201	139,768,554
Total	5,105,414	883,222	5,988,636	139,768,554

much of a workplace benefit of vaccination, because as the Puhach study shows (its figure 4), the effect of the vaccine is to shorten the viral load by about 2 days at the end of the infectious process. At this point, symptomatic and test-positive employees are largely isolating at home, so the clearance issue concerns risks of transmission at home but not much in the workplace.

On August 6, 2021, CDC posted an article (<u>Brown et al., 2021</u>) in its in-house journal, *Morbidity and Mortality Weekly Reports*, describing the large Covid-19 case outbreak that happened over the July 4 weekend in Provincetown, MA, where 346 (74% of) cases were found in "fully vaccinated" persons. Some 90% of the case infection strains were identified as the Delta variant.

Also on August 6, 2021, CDC Director Rochelle Walensky publicly confirmed that persons who receive a Covid-19 vaccine and are totally asymptomatic can still pass on the virus to someone else, and that while the Covid-19 vaccine may [so she said] help regarding reducing the severity of the symptoms of those who catch Covid-19, "what they can't do anymore is prevent transmission." https://www.youtube.com/watch?v=TKFWGvvlVLI (August 6, 2021, CDC Director, CNN interview, timestamp 0:56 to 1:56).

Breakthrough infections were also seen among fully vaccinated health-care workers at the Hospital for Tropical Diseases in Ho Chi Minh City, Vietnam, which used the Oxford-AstraZeneca vaccine (Chau et al., 2021). Between June 11-25, 2021 (7-8 weeks after the second dose), 69 of the hospital's 866 workers tested positive for SARS-CoV-2. This comprises 8% of the workers over the 2-week period, but because the hospital was locked down June 12-26, 2021, with no one allowed to enter or leave, the infection transmission estimate may have been affected by the lockdown.

Starting April 2021, CDC was monitoring Covid-19 vaccine breakthrough cases. The monthly data from April through December 2021 were initially made <u>publicly available</u> October 21, 2021 (and still are). The table above provides the CDC data on numbers of breakthrough infections, along with

Figure 3. Household Secondary Attack Rates (SARs) by Index Case Vaccination Status Estimates Study, location Infected Total SAR (95% CI) Unvaccinated Alpha Partially vaccinated de Gier et al, 19 2021; Netherlands Fully vaccinated Unvaccinated 43069 0.31 (0.31-0.31) Partially vaccinated 0.29 (0.27-0.31) Booster vaccinated 587 2032 Fully vaccinated 79 706 0.11 (0.09-0.14) Gazit et al, 21 2021; Israel Unvaccinated 1005 2814 0.36 (0.34-0.37) Fully vaccinated 21 269 0.08 (0.05-0.11) Layan et al, 28 2021; Israel 641 0.41 (0.37-0.45) Unvaccinated 261 Fully vaccinated 43 0.19 (0.08-0.32) Meyer et al.33 2021; Germany 12 22 0.55 (0.33-0.75) Unvaccinated Fully vaccinated 0.22 (0.01-0.56) 44347 0.363 (0.313-0.416) Unvaccinated estimate 143279 0.107 (0.090-0.128) Fully vaccinated estimate 110 1027 Delta de Gier et al, 70 2021; Netherlands Unvaccinated 711 4022 0.18 (0.17-0.19) Partially vaccinated 735 0.08 (0.06-0.10) Fully vaccinated 294 2373 0.12 (0.11-0.14) Del Águila-Mejia et al, 61 2022; Cantabria, Spain Unvaccinated 0.53 (0.50-0.56) 595 1118 Fully vaccinated 519 1198 0.43 (0.41-0.46) Jalali et al,64 2022; Norway 0.38 (0.33-0.42) Unvaccinated 158 420 Partially vaccinated 71 0.39 (0.28-0.51) Fully vaccinated 127 360 0.35 (0.30-0.40) 0.11 (0.00-0.29) Booster vaccinated 2 19 Lyngse et al,65 2022; Denmark 8562 0.22 (0.22-0.23) Unvaccinated Fully vaccinated 0.20 (0.19-0.21) 3069 15248 Ng et al, 37 2021; Singapore Unvaccinated 127 552 0.23 (0.20-0.27) 0.21 (0.11-0.32) Partially vaccinated 63 Fully vaccinated 29 138 0.21 (0.15-0.28) Singanayagam et al, 42 2022; UK 23 100 0.23 (0.15-0.32) Partially vaccinated 35 0.37 (0.22-0.54) Fully vaccinated 17 69 0.25 (0.15-0.36) Unvaccinated estimate 10176 44548 0.283 (0.199-0.386) Partially vaccinated estimate 112 904 0.225 (0.112-0.401) Fully vaccinated estimate 4055 19386 0.248 (0.172-0.343) Baker et al,⁶³ 2022; US Unvaccinated 69 108 0.64 (0.55-0.73) 1.00 (0.68-1.00) Partially vaccinated Fully vaccinated 103 200 0.51 (0.45-0.58) 47 110 0.43 (0.34-0.52) Booster vaccinated Del Águila-Mejia et al, 61 2022; Cantabria, Spain Unvaccinated 171 354 0.48 (0.43-0.54) Fully vaccinated 85 171 0.50 (0.42-0.57) Jalali et al,⁶⁴ 2022; Norway Unvaccinated 187 329 0.57 (0.51-0.62) Partially vaccinated 154 0.42 (0.34-0.49) Fully vaccinated 363 713 0.51 (0.47-0.55) Booster vaccinated 47 103 0.46 (0.36-0.55) Lyngse et al,62 2022; Denmark Unvaccinated 1359 3500 0.39 (0.37-0.40) Booster vaccinated 3786 0.30 (0.29-0.32) 1786 4291 0.512 (0.419-0.605) Partially vaccinated estimate 69 159 0.768 (0.077-0.992) 0.508 (0.479-0.538) Fully vaccinated estimate 551 1084 Booster vaccinated estimate 1247 3999 0.380 (0.299-0.468) 0.25 0.5 0.75 SAR (95% CI)

the CDC's estimated monthly cumulative numbers of Americans receiving the Covid-19 vaccinations. By the end of 2021, almost 6 million vaccinated people had become infected according to these data. This comprises 4.3% of the 140 million Americans who had been vaccinated by that time. However, this number of cases is also likely a very large undercount, because CDC stopped documenting post-

vaccine infections at the beginning of May 2021 unless the person was hospitalized for Covid-19 or had died of it. Given that hospitalization and death involved a minority of all Covid-19 cases, including breakthrough cases—12% according to <u>CDC</u>—the breakthrough case risk among vaccinated people in this time period was very likely many-fold greater than the 4.3% estimated.

Thus, it is clear that at the time the Washington state and WDFW employee Covid-19 vaccine mandates were enforced in 2021, appreciable risks of breakthrough infections were evident, making the vaccines substantially imperfect for the supposed role of reducing infection risk, and data supporting this observation were publicly available at the time.

Covid-19 Vaccine Effects on Virus Transmission: Secondary Attack Risks

The second component of transmission risk is whether the vaccines served as effective source control among people who got infected anyway. Studies of this property of the Covid-19 vaccines have generally been conducted in circumstances where the individuals at secondary risk of infection can be explicitly enumerated, such as among household members or prison inmates, or in long bus rides. These studies all involve infected primary index cases, so that estimated secondary attack risks (SARs) largely reflect transmission risks in the physical-temporal circumstances of the studies, rather than vaccine effects on risks of primary infection.

A major summary analysis of Covid-19 SARs in household settings was published by <u>Madewell and colleagues (2022)</u> (appeared on <u>medRxiv</u> January 11, 2022), dividing up the time periods by predominant circulating virus strain variant: Alpha, Delta and Omicron. The study identified that the Delta variant was the commonly circulating strain during the second half of calendar year 2021 (Figure 1 in the Madewell et al. paper).

The Madewell et al. summary household SARs by index case vaccination status are shown in the figure at the top of the previous page (blue and black diamonds). In the Alpha period of the first half of 2021, vaccination appreciably reduced risk of secondary household transmission, from 36% for unvaccinated index cases, to 11% for vaccinated index cases. However, for the Delta period of the second half of the year, the main period of concern of the WDFW mandate, the fact of vaccination of the index case made little tangible benefit for risk of household transmission, 28% for unvaccinated index cases and 25% for vaccinated index cases, a difference not nearly statistically significant across the six studies included in the analysis. Omicron also shows no difference in SAR between unvaccinated and fully vaccinated (presumably 2-dose vaccination) index cases. One minor point about the Madewell data shown in the figure on the previous page is that the results are not adjusted for vaccination or Covid infection history of the secondary household contacts. Only a few of the included studies had information on contact vaccination history, and none on infection history. Thus, limiting the meta-analyses to such studies would make the results substantially less representative of the full evidence examined.

From these various cited studies and data, I conclude that the Covid-19 mRNA vaccines in use in the US during the second half of 2021, when the Delta strain was circulating were, as a 2-dose regimen, relatively weak in substantially reducing infection transmission. Post-vaccination breakthrough infections were commonly occurring, and the vaccines in that period only partially stopped secondary transmission of infections. Information supporting this conclusion was publicly available during the latter half of 2021.

Agency Vaccine Verification DATA						
Agency	Headcount ¹	Vaccine Verification Rate (Tot HC) ¹	Headcount ²			
DFW	1,900	96.84%	1,876	98.08%		

Report provided by Office of Financial Management based on state agency submitted data.

Report Release Date: January 12, 2022

<u>Issues Specific to Plaintiffs and to Undue Hardship</u>

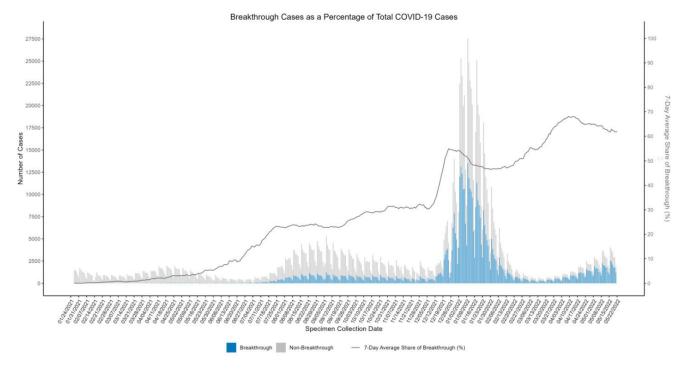
By the term "undue hardship" I mean a degree of risk that would generate substantial action to prevent or remediate it. I am not using this term in its legal sense per se. <u>EEOC</u> uses this term in evaluating semi-quantitative degrees of infection-associated risks, and my intent is to address scientific evidence for quantitatively estimating degrees of risk as discussed by EEOC, below.

General Comments About Covid Transmission Risks by Vaccinated and Unvaccinated Individuals

During the pandemic, Washington State maintained a database for state employee vaccination tracking. These <u>vaccination data</u> were captured on the internet January 27, 2022 as reported for January 12, 2022 (image above: WDFW employee data graphically extracted from the pdf tables). At that time, these data show that 1,876 WDFW employees were subject to the vaccine mandate. Of these, 98.08% were vaccinated in compliance with the vaccine mandate, and 36 were unvaccinated and had been terminated. These unvaccinated thus comprised 1.9% of the WDFW employees.

Among these 1,876 WDFW employees, the <u>CDC data</u> estimate that 4.3% of them, 81 in total, would have been expected to have had Covid-19 post-vaccination breakthrough infections, i.e., Covid-19 infections through vaccine failure during 2021. In comparison, of the 36 terminated unvaccinated individuals, 1.9% of the workforce, even if 100% of them had gotten Covid-19 during the same time period, the total infection load among these unvaccinated (n=36) would have been less than half the total infection load among the vaccinated (n=81). This is also consistent with the at minimum 5-6% breakthrough infection risk from the vaccine efficacy RCT studies.

Furthermore, Washington State Department of Health knew throughout the Delta period of the second half of 2021, that large numbers of Covid-19 breakthrough infections were occurring in vaccinated individuals in the state. The figure at the top of the next page shows that during this period, roughly 25% of all registered Covid-19 cases were breakthrough infections (blue shading), more than 80,000 (Washington State Department of Health, 2022a). In addition: "From January 17, 2021 - January 1, 2022, there have been 123,365 vaccine breakthrough cases identified in Washington State. To date, more than 4.8 million people in Washington state are up to date on their vaccines. The breakthrough cases represent a small portion, about 2.5% of the vaccinated population." (Washington State Department of Health, 2022b). While there has been some serious discussion about the poor and unreliable quality of Washington State Department of Health statistics (Knopik, 2024), the 2.5% reported breakthrough figure is still larger than the 1.9% fraction of WDFW unvaccinated terminated employees.



Because of this very small potential infection load had all terminated employees just maintained their regular job positions, all assertions that the presence of unvaccinated staff in non-accommodatable positions would have reduced public and staff safety, are illogical, since breakthrough infections of the vaccinated staff, given their larger numbers, would have caused more public "unsafety" than infections among the unvaccinated. WDFW took no mandate measures to require booster vaccines for the vaccinated, thus institutional concerns about *vaccinated* staff causing Covid-19 "undue hardship" did not arise, even though vaccinated breakthrough infections comprised a larger infection load than infections that the unvaccinated might have had, had they not been terminated and had they been accommodated specifically by working in place in their usual jobs. Given that the breakthrough infection load of the vaccinated employees was not *undue* hardship—WDFW took it in stride—the smaller infection load of these unvaccinated individuals had they not been terminated cannot be *undue* hardship.

WDFW also hired replacement workers for the terminated employees (Complaint, par. 48), replacements who were not required to be vaccinated. WDFW took this potential infection load in stride as well: no *undue* hardship from these potentially unvaccinated employees.

I would also note that my discussions above about the risk from infection load as a totality among vaccinated employees and among unvaccinated employees applies equally at the in-person interaction level, as probabilities. That is, a person coming in contact with a WDFW employee would be more likely to be exposed to a breakthrough infection in a vaccinated employee, than to an infection in a rare unvaccinated employee, had such employees just remained working in place in their usual jobs.

Potential Risk Burden Posed by Plaintiffs

Plaintiffs were all granted religious exemptions, and a few were granted medical exemptions as well, but then all were refused accommodations and terminated. Even though most of the Plaintiffs' job activities were carried on outdoors or by telework, Defendants asserted that meetings with

supervisors (who were themselves presumably vaccinated) had to be done indoors, in-person, which therefore made the jobs non-accommodational by virtue of claimed excess risk to supervisors.

In my opinion concerning the degree of potential infection transmission associated with these jobs, I cite the <u>EEOC rules</u> for what EEOC calls reasonable accommodation (section L.3), which describes semi-quantitative examination of potential Covid-19 infection risks:

"An employer will need to assess undue hardship by considering the particular facts of each situation and will need to demonstrate how much cost or disruption the employee's proposed accommodation would involve. An employer cannot rely on speculative or hypothetical hardship when faced with an employee's religious objection but, rather, should rely on objective information. Certain common and relevant considerations during the COVID-19 pandemic include, for example, whether the employee requesting a religious accommodation to a COVID-19 vaccination requirement works outdoors or indoors, works in a solitary or group work setting, or has close contact with other employees or members of the public (especially medically vulnerable individuals). Another relevant consideration is the number of employees who are seeking a similar accommodation, i.e., the cumulative cost or burden on the employer." [bolding mine]

According to this standard, just the assertion that Plaintiffs posed excess Covid-19 infection risks is insufficient to establish the degree (i.e., the *undue*) of hazard. This falls into the category, speculative or hypothetical hardship, that the EEOC rule prohibits. The considerations enumerated in the above EEOC paragraph clearly set out to approximate the quantitative degree of risk posed by the unvaccinated employee in the accommodation role. Further, the "number of employees" and cumulative burden considerations explicitly include the total infection risk burden, exactly what I have quantitatively evaluated above according to CDC data and Washington State Department of Health data available around the time of WDFW's implementation of the Washington State mandate Proclamation.

WDFW generally asserted that unvaccination of Plaintiffs created *undue* hardship but presented no quantitative evidence of such other than the assertion that unvaccinated people had higher risk. Because of the quantitatively small number of the unvaccinated terminated staff, the cumulative hardship would not have been *undue*. The majority of Plaintiffs had already had Covid-19 and presented documentation of their immunity status, which was ignored by Defendants in their claims that Plaintiffs posed unacceptable excess infection risks.

Summary: Scientific Essence of the Case:

- By October 18, 2021, the State of Washington <u>mandated</u>, for employees of various state agencies, full (2-dose) Covid-19 vaccination. The state mandate allowed for accommodations for medical and religious exemptions.
- Legal precedent established that rejection of religious exemption accommodations, otherwise allowed under the state mandate, could be done where accommodation would cause undue hardship to the agency or employer.

• WDFW asserted that Plaintiffs' claimed higher infection risks as unvaccinated workers caused WDFW undue hardship, as well as posed undue hardship to vaccinated employees, and terminated Plaintiffs' employment.

Summary: Scientific Essence of the Counterargument:

- CDC empirical data from 2021 showed that post-vaccination breakthrough Covid-19 infections in that time period occurred in at least 4.3% of vaccinated individuals; Washington State Department of Health data put this figure at 2.5%.
- In the WDFW workforce, the fraction of mandated employees terminated from employment for unaccommodated religious exemption requests, 1.9%, is less than this 4.3% (or 2.5%) number. Thus, even if all such individuals had been given accommodations to continue working in their existing positions, and even if every one of them got Covid-19 in this time period, the infection burden in total among these unvaccinated staff would have been less than the infection burden in total among the great majority of staff who had been vaccinated.
- While infectivity of Covid-19 infections among unvaccinated people tends to last longer than among vaccinated people by a day or two, this tail end of the infectivity period occurs when people are almost always at home pending resolution of their symptoms or test-positivity quarantine, thus is of no consequence for infection burden in the workplace.
- WDFW took no action to mandate booster vaccine doses to vaccinated staff, thus demonstrating that it took in stride the larger total infection load among the vaccinated staff, which thus did not create an *undue* hardship for WDFW. On this basis, the smaller infection load among the unvaccinated terminated staff, had they been granted religious exemption accommodations and remained employed, cannot be claimed to create an *undue* hardship.
- Virtually all of the evidence for the above was available in 2021, and Covid-19 booster doses were available starting September 2021.

I reserve the right to review additional materials and supplement my opinions if necessary.

My fee is \$600 per hour.

Date: November 28, 2024

Harvey A. Risch, M.D., Ph.D.

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